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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,771	12/05/2005	Mohammad Reza Mehrabi	TOMK0004	9945

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EXAMINER	
THOMAS, TIMOTHY P	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
09/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,771	MEHRABI, MOHAMMAD REZA	
	Examiner	Art Unit	
	Timothy P. Thomas	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12, drawn to a method for producing a medicament comprising alprostadil.

Group II, claim(s) 1-12, drawn to a method of stimulating angiogenesis.

Note: The claims have been written as "use" claims of the drug alprostadil. They have been interpreted in the two ways described in by the above groups. It is also possible that some of the dependent claims may be interpreted as drawn to a method of treating one or more conditions or diseases, e.g., claim 6 might also be interpreted as drawn to a method to treat a patient that has suffered a myocardial infarction, comprising (the unclaimed step of) the administration of alprostadil to a patient after a myocardial infarction. However, such alternate subject matter will be examined along with group II, and will be considered upon clear amendment of the claims to reflect such intent and election of group II and the corresponding specie, from the listing below. It is recommended that applicant amend the claims before the first action on the merits to clearly claim applicant's intention and to clearly identify the steps that are associated with the elected method.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As described in the note above, the claims have been drafted as "use" claims, which may be interpreted as drawn to either of two different methods that involve the drug alprostadil (also known as prostaglandin E1, PGE1). A method for producing a medication would presumably involve steps related to the formulation of the medicament; a method for stimulating angiogenesis would presumably involve steps of administration of alprostadil to a subject.

The technical feature common to the claims is alprostadil or alprostadil associated with angiogenesis. Diaz-Flores, et al. (The Anatomical Record; 1994; 238:68-76; IDS reference) teaches PGE1 induces capillary sprouting from veins in soft connective tissue from the rat femoral vein and neovascularization (abstract). Since the technical feature has been disclosed in the prior art, the technical feature does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the priot art. Accordingly, Groups I-II are not so linked by the same or a corresponding special technical feature as to form a single inventive concept.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If applicant elects Group II, applicant must also elect a specific condition or disease that the angioneogenesis is used for from the following:

(i) treatment of cardiomyopathy (claim 2);

(ii) treatment of chronic heart failure (claim 2);

(iii) treatment of (i) and (ii) (claim 2);

(iv) neovascularization (claim 3);

(v) reduction of the degree of fibrosis (claim 4);

(vi) regression of hypertrophy (claim 5);

(vii) revitalization of dead areas of the heart (claim 6);

(viii) treatment of advanced peripheral arterial occlusive diseases (claim 7);

(ix) treatment of diabetic angiopathy (claim 8);

(x) treatment of pulmonary fibrosis (claim 9);

(xi) treatment of systemic lung disorders, not included in (x) (claim 9);

(xii) treatment of renal failure and glomerulonephritis (claim 10);

(xiii) treatment of hepatic failure (claim 11);

(xiv) treatment of cerebral infarction (claim 12); or

(xv) any other singly disclosed condition or disease not in (i)-(xv) (specify the specific condition or disease) (claim 1).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

The specific conditions correspond to the claims designated above

The following claim(s) are generic: claim 1.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As pointed out above the prior art has disclosed neovascularization associated with the administration of PGE1 to tissues surrounding rat femoral vein. Therefore the technical feature common to the species does not constitute as special technical feature and as it does not define a contribution over the prior art; the species are not linked by the same or a corresponding special technical feature as to form a single inventive concept.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy P. Thomas whose telephone number is (571) 272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TPT/
Timothy P. Thomas
Patent Examiner

Ardin H. Marschel 9/22/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER